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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/535,687	05/19/2005	Christopher John Knowles	BOUL/0016	4285
26290 7590 10/09/2007 PATTERSON & SHERIDAN, L.L.P. 3040 POST OAK BOULEVARD SUITE 1500 HOUSTON, TX 77056			EXAMINER FERNANDEZ, SUSAN EMILY	
			ART UNIT 1651	PAPER NUMBER
			MAIL DATE 10/09/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	Application No. 10/535,687	Applicant(s) KNOWLES ET AL.	
	Examiner Susan E. Fernandez	Art Unit 1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☒ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>5/19/05, 10/17/05, 3/17/06</u> . | 6) <input type="checkbox"/> Other: ____.  |

### **DETAILED ACTION**

The preliminary amendment filed May 19, 2005, has been received and entered.

#### ***Information Disclosure Statement***

The information disclosure statement filed May 19, 2005, fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered.

#### ***Claim Objections***

Claim 16 is objected to because of the following informalities: The word "microbial" should be inserted before the word "cultures". Appropriate correction is required.

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 12 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 12 is indefinite since the recitation "the biocatalysis reaction mixture containing active biomass" lacks antecedent basis. Parent claims 1, 6, and 7 do not recite any "active

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biomass.” Moreover, claim 12 is confusing since it is unclear how the biocatalysis reaction and the electrodialysis can be operated in separate reactors given that electrodialysis is necessary for the application of a direct current electric field to the reaction mixture which undergoes biocatalysis.

### *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4, 6, 7, 13, and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by GB 1217035.

GB '035 discloses “...a method of controlling the oxidation of a carbohydrate or polyhydric alcohol comprising treating a feedstock containing the carbohydrate or polyhydric alcohol with an oxidizing agent to form a reaction mixture containing a monocarboxylic acid; and removing the monocarboxylic acid during formation thereof so that the feedstock is maintained in the reaction mixture at a concentration greater than that of the monocarboxylic acid” (page 1, lines 76-87). Moreover, such a process is taught for the preparation of lactic acid by fermentation (page 3 lines 60-74). The process may be carried out by using electrochemical oxidation in an electrolyzer (page 2, lines 37-40), and the oxidizing agents may be enzymes or bacteria (page 2, lines 41-44). Figure 2 shows an embodiment of the invention. The reaction mixture is sent into a reactor vessel wherein an anion exchange membrane (2) separates the

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reaction mixture from the cathode (4), and a cation exchange membrane (3) separates the reaction mixture from the anode (5) wherein the electrodes apply an electric field (page 3, lines 90-95). Clearly the electrodes do not come into contact with the reaction mixture, as they are separated by separation membranes. Figure 2 also demonstrates that the electric field applied is a direct current (DC) field. Thus, claims 1-4, 6, 13, and 14 are anticipated. Claim 7 is also anticipated given the teachings at lines 108-113 on page 3.

A holding of anticipation is clearly required.

### *Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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Claims 1-8, 13, and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over GB 1217035 in view of Xu (Desalination. 2001. 140: 247-258. listed on IDS).

As discussed above, GB '035 anticipates claims 1-4, 6, 7, 13, and 14. However, GB '035 does not expressly disclose that a bipolar ion exchange membrane is used as the ion exchange membranes used in the device for practicing the GB '035 invention.

Xu discloses the advantages of using a bipolar ion exchange membrane in electrolysis processes, pointing out that its use results in lower energy consumption, and that since it does not generate gases from electrodialytic water splitting, there is no corrosion to both cathode and anode (page 247, second column). Moreover, Xu points out that "bipolar membrane water splitting technology provides an ideal complement to the fermentation technology by removing the product acid while simultaneously providing an equivalent amount of base for use in adjusting the pH in the fermentor" (page 253, first column, last paragraph).

At the time the invention was made, the person of ordinary skill in the art would have been motivated to have used a bipolar ion exchange membrane in the electrolyzer utilized for performing the GB '035 invention. One of ordinary skill in the art would have been motivated to do this given that it lowers energy consumption, avoids electrode corrosion, and removes the product acid (monocarboxylic acid). Thus, a holding of obviousness is clearly required.

Claims 1-11 and 13-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over GB '035 and Xu as applied to claims 1-8, 13, and 14 above, and further in view of Egen et al. (US 5,336,387), Hongo et al. (Applied and Environmental Microbiology. 1986. 52(2): 314-319), and Nomura et al. (Biotechnology and Bioengineering. 1987. 30: 788-793).

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As discussed above, GB '035 and Xu render claims 1-8, 13, and 14 obvious. However, these references do not expressly disclose that the reaction mixture comprises a cationic buffer system with an organic product forming an anionic component.

Egen et al. discloses that a buffer comprising tris is a suitable buffer for an electrodialysis system (column 19, lines 19-23).

At the time the invention was made, it would have been obvious to the person of ordinary skill in the art to have used a tris buffer, which is a cationic buffer, in the process of GB '035 wherein an electrolyzer is used. One of ordinary skill in the art would have been motivated to do this since the person of ordinary skill in the art would have recognized the suitability of using a tris buffer in any electrodialysis system.

Additionally, the references differ from the claimed invention in that the references do not disclose that the DC electric field applied is adjusted to control the pH of the reaction mixture.

Hongo et al. discloses an electrodialysis fermentation process wherein fermentation broth is passed into an electrodialyzer for the removal of produced lactic acid (abstract and page 315, first column). The pH of the reaction mixture is monitored, and when the pH falls below the set pH value, the direct-current power supply connected to a pH controller is operated to cause a flow of electric current which then results in an increase in pH (page 315, first column, last paragraph through page 315, second column, first paragraph).

At the time the invention was made, the person of ordinary skill in the art would have been motivated to have adjusted the DC electric field to control the pH of the reaction mixture of the GB '035 invention. One of ordinary skill in the art would have been motivated to do this

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since DC electric field is shown to be suitable for the adjustment of the pH of a reaction mixture in a electrodialysis system. Moreover, it would have been particularly suitable for maintaining the pH of a reaction mixture for the production of lactic acid, which is disclosed as Example 3 of GB '035 (page 5, line 125 through page 6, line 71). In controlling the DC electric field, it would have been obvious to have used a computer program since such a program would be necessary for the operation of the pH controller (programming necessary for adjusting the DC electric field according to the detected pH).

The references also differ from the claimed invention in that they do not expressly disclose that immobilized cultures are used in the GB '035 process.

Nomura et al. discloses immobilized growing bacterial cells entrapped in calcium alginate for use in lactic acid production occurring in an electrodialysis system (page 788, second column, second paragraph). The immobilization of cells resolves problems occurring when free microbial cells are used: "...microbial cells in the fermentation broth gradually attach to the anion-exchange membranes, causing an increase in electric resistance and a decrease in the efficiency of electrodialysis" (page 788, first column, last sentence through second column, first paragraph).

At the time the invention was made, it would have been obvious to the person of ordinary skill in the art to have used immobilized growing bacterial cells entrapped in calcium alginate as the bacterial culture for performing the GB '035 invention. One of ordinary skill in the art would have been motivated to do this in order to have prevented the attachment of microbial cells to the anion-exchange membrane, which would have caused an increase in electric resistance and a decrease in the electrodialysis efficiency.



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Thus, a holding of obviousness is clearly required.

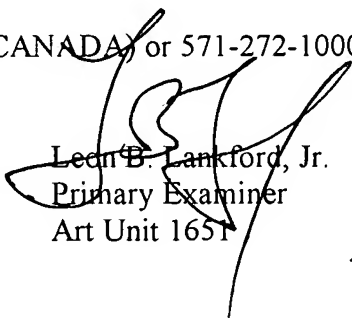
No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan E. Fernandez whose telephone number is (571) 272-3444. The examiner can normally be reached on Mon-Fri 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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